

Version With Markings to Show Changes Made

In the Claims

22. (Amended) A solid pharmaceutical dosage form adapted for direct oral administration across the oral mucosa comprising:

a pharmaceutically effective amount of an orally ~~administerable~~administrable medicament; and

at least one saliva activated effervescent ~~agent~~couple present in an amount between about 5% by weight and about 80% by weight.

52. (Amended) The method of administering at least one systemically distributable pharmaceutical agent according to claim 17, wherein said non-effervescent disintegration agent is selected from the group consisting of microcrystalline cellulose, ~~erose~~armelose~~croscarmellose~~ sodium, crospovidone, corn starch, potato starch, modified corn starch, modified potato starch, bentonite, alginates, agar, guar, locust bean, karaya, pectin and tragacanth.

~~52~~2. (Amended) The method of administering at least one systemically distributable pharmaceutical agent according to claim 37, wherein said medicament is prochlorperazine.

REMARKS

Entry of the foregoing and reexamination and reconsideration of the above-captioned application, pursuant to and consistent with 37 C.F.R. §§ 1.112 and 1.116 are respectfully requested. Because applicants' comments and amendment should place the application in condition for allowance and/or, at the very least, reduce the issues for appeal, applicants respectfully request entry and consideration of the following information.

Upon review of the Official Action, applicants noted that claims 17 and 22-~~82~~ are pending. However, claims 17 and 37-82 have been withdrawn from consideration. In the Amendment dated March 25, 2002, applicants inadvertently numbered two claims as claim 52. Applicants have renumbered one of these claims as claim 82 to eliminate any confusion. In addition, two typographical errors were found in withdrawn claims. Applicants seek to correct these also.

Claim 22 and the claims dependent therefrom have been rejected pursuant to 35 U.S.C. § 102 over DiSanto. To the extent that that rejection would be applied to the claim as amended, Applicants respectfully traverse. The examiner has argued that the amount of sodium bicarbonate recited in example 3 of DiSanto is 61% and, accordingly, DiSanto reports an amount of effervescent material falling within the range of 5 to 80% as claimed in claim 22.

Claim 22 referred to an effervescent "agent." As explained at page 5 of the specification, the term "effervescent agent" includes compounds that evolve gas. The preferred effervescent agents evolve gas by means of a chemical reaction, which takes place upon exposure of the effervescent agent (an effervescent couple) to water and/or to saliva in the mouth. Accordingly, it is inconsistent with both applicants' definition and the common definition of effervescence to consider only the weight percentage of the sodium bicarbonate without also consideration of, at the very least, the citric acid recited within example 3. If citric acid is considered, then the amount of effervescent material is well above 80% as claimed. Therefore, the DiSanto reference cannot anticipate the claim.

To alleviate any possible ambiguity, applicants have amended claim 22 to delete the term "agent" and to specifically refer to an effervescent "couple." As noted above, these terms are of identical scope and are clearly supported by at least the specification at page 5 quoted above.

This amended claim clearly and unambiguously establishes that example 3 of DiSanto cannot anticipate the claimed invention as it describes an amount of effervescent couple that is far more than 80% as claimed.

The claims have also been rejected as being obvious. However, applicants respectfully traverse. If DiSanto does not anticipate the claimed invention (which it does not), it cannot possibly render them obvious. DiSanto provides nothing more than a single example, with essentially no explanation, of a particular effervescent formulation for one drug. It provides no discussion of modifying that formulation in any way.

There is nothing in DiSanto to teach, suggest or motivate one of ordinary skill in the art to modify the amount of the effervescent couple recited in example 3. Indeed, applicants have been unable to find another reference to effervescents anywhere in the specification.

Nothing in the DiSanto reference teaches or suggests that the amount of effervescents used can be important for purposes of transporting material across the mucosal membrane in the mouth nor that particular amounts of material are preferred for this purpose. In short, other than a solitary serendipitous disclosure of a formulation with little or no explanation, DiSanto is not a relevant teaching at all of anything broader. One of ordinary skill in the art could not look at example 3 and, based upon its teaching, arrive at the present invention. DiSanto does not suggest the goal of improved absorption through use of effervescents, or even suggest a manner in which that can be achieved. And the secondary reference in no way addresses these deficiencies.

With all due respect, the examiner has engaged in a hindsight reconstruction of the invention, arguing that it would be obvious to amend the amount of effervescents used in the DiSanto reference to arrive at the present invention. However, in view of the complete absence on the current record of anything suggesting the modification of the amount of effervescents used, and how and why someone would want to do same in this context, applicants are using the claims a blueprint and reconstructing the invention from discrete elements in the art. Applicants respectfully submit that the Patent Office has failed to establish a *prime facie* case of obviousness.

In view of the foregoing, applicants ask for reconsideration of the claims, as amended. Should the examiner have any questions with regard to the foregoing, the examiner should contact the undersigned, at the examiner's convenience, at 908 654 5000. Furthermore,

should any fee be due and owing in this regard, the examiner is authorized to charge deposit account no. 12-1095 therefor.

From the foregoing, further and favorable action in the form of a notice of allowance is believed to be next in order and such action is earnestly solicited.

Dated: June 27, 2002

Respectfully submitted,

By 

Michael H. Teschner

Registration No.: 32,862

LERNER, DAVID, LITTENBERG,

KRUMHOLZ & MENTLIK, LLP

600 South Avenue West

Westfield, New Jersey 07090

(908) 654-5000

Attorneys for Applicant